Public Health Service
Food and Drug Administration

DEPARTMENT OF HEALTH & HUMAN SERVICES

MA211n

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

VIA FEDEX

WARNING LETTER

September 20, 2000

Our Reference: 2431026

James J. Kelly, President and CEO
Carl Zeiss, Inc.
1 Zeiss Drive
Thornwood, New York 10597

Dear Mr. Kelly:

On April 12 and 13, 2000 your firm offered for import into the United States two shipments of medical device lasers under entries 004-8199234-5 and 004-8200397-7. Our office detained these entries on April 14, 2000. Telephone conversations with, and documentation obtained from the ultimate consignee, [redacted] indicates that the seven lasers that comprised these two entries have been distributed into commerce without proper release from FDA. This is a violation of Title 21 Code of Federal Regulations, Section 1.90, which requires the importer to hold an entry intact pending receipt of a May Proceed or Release Notice from FDA.

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or detention without physical examination of future shipments. It is your responsibility, as the importer, to ensure that the imported product meets all requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

Please notify this office in writing, within 15 days of receipt of this letter, of the specific steps you have taken to prevent recurrence of the noted violations. Your written reply should be addressed to the Food and Drug Administration, Attention: Mr. Russell A. Campbell, Compliance Officer, 1431 Harbor Bay Parkway, Alameda, CA 94502.

Sincerely,

Kris A. Foster

Kris A. Foster
Acting Director

cc: [redacted]